

SPL R4 Common Errors as of December 2009

This document is to be utilized by SPL document authors as a reference to determine the source of common errors in SPL documents submitted to FDA.

NDC Labeler Code SPL Documents

Error Message	Solution
The id with the root 2.16.840.1.113883.6.69 must not be associated with any other document of type "NDC Labeler Code request" with a different setId	Do not submit the same NDC labeler code in a different SPL which has a different setId.
One id has the root 2.16.840.1.113883.6.69 and an extension (except for an initial labeler code request, which should be submitted without this id)	Include the labeler code in the NDC Labeler Code number field unless you are requesting a labeler code. If you are requesting a labeler code then delete the NDC Labeler Code field.
The id extension with the root 2.16.840.1.113883.6.69 has 4 or 5 digits	Enter an already assigned labeler code using 4 or 5 digits. Do not include leading zeros that are not included in the labeler code segment of the 10-digit NDC

Establishment Registration SPL Documents

Error Message	Solution
id must not be associated with any other set id for document type "Establishment registration"	DUNS Number for registrant is associated with only one Establishment Registration SPL's setId.
The id with the root 1.3.6.1.4.1.519.1 along with the establishment postal code (if any) and country must match the DUNS number, postal code and country in the Dun and Bradstreet database	Ensure that the DUNS Number and address for a drug establishment is correct . Check to be sure that you have added the ISO 3166-1 3-letter country code.
The id must not be associated with another establishment in the same SPL file.	Do not use the same DUNS Number for two different drug establishments in the same SPL file. Obtain the DUNS Number for each site.

The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, DO NOT add “import” or “united states agent” as a type of operation for an establishment. Include “import” or “united states agent” in the Importer or United States Agent fields – NOT the type of operation for a drug establishment
an email address is of the simple form <username>@<dns-name>	<ul style="list-style-type: none"> - Enter a valid e-mail address - Remove spaces located before or after e-mail address that were created with keyboard space bar.
Content of Labeling & Listing SPL Documents	
Error Message	Solution
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there must be no id.	<p>Remove the application or citation number or application and citation number code system for products which do not have application or citation numbers.</p> <p>Delete the empty application or citation number field. You may have to request to have the empty ID element removed if you still receive error after following above steps.</p>
If the marketing category code is not C73626 (bulk ingredient) or C73613 (unapproved medical gas), then there must be at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.	<p>With the exception of bulk ingredient and medical gas product SPL documents, include each section of the content of labeling (package insert or drug facts) in the appropriate SPL content of labeling section.</p> <p>Use the appropriate section header for each section. Add a section GUID, title, etc...</p> <p>This means that all other drug products should have a content of labeling sections.</p> <p>DO NOT include an image of the content of labeling. Enter the text or table from the package insert or drug facts in the appropriate sections SPL content of labeling.</p>
Name must match the code	Use the preferred name and UNII in the UNII list. If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov
There is a section with the code 51945-4 (principal display panel) with a jpg file (carton/container label).	Include each representative sample of a carton/container label in a major SPL section with section heading “Package.Label Principal Display Panel. (one carton/contain label image per section)

Remove additional qualifiers (e.g. dosage form, route of administration, etc...) from product names in the product data elements section.	Remove dosage form, route of administration, etc... from the product name(s) in the product data elements section of the SPL document.
Reference value must be the file name for the image	Ensure that you have referenced the image in the appropriate content of labeling section - If you are using the Pragmatic Data Validator Lite tool, zip the image with the SPL document and upload the zip file. HOWEVER, DO NOT send a zip file to FDA. - Ensure that you have placed the image in the folder that has the SPL document.
Size of image file is less than 1 MB	Reduce the size of each image file to under one megabyte (MB)
First segment matches an NDC Labeler Code associated with the Labeler id.	Ensure that the labeler code and labeler's DUNS Number is identical to the labeler code and labeler's DUNS Number in your drug listing SPL document.
The setID is not associated with any top level product with a different NDC Labeler Prefix	Do not use different labeler codes in the same SPL document. Create another SPL for products associated with a different labeler code.
If the marketing status code for any of the products is not "completed," then there are one or more establishments	Include at least one establishment if any of the products described in the SPL is still being marketed (has a marketing status of "Active") If all of the products in the SPL are discontinued (has a marketing status of "Completed") then a drug establishment does not have to be included in the listing SPL document.
Name contains no special symbols (e.g., no "®" or "™" etc) and no "USP"	Do not include symbols or "USP" in the proprietary name of the products in the product data elements section. NOTE: Do not include the dosage, route or strength in the proprietary name field
Generic medicine name contains no special symbols (e.g., no "®" or "™" etc) and no "USP"	Do not include symbols or "USP" in the generic/established name of the product in the product data elements section. NOTE: Do not include the dosage, route or strength in the generic name field
If the products has parts, then the form code is C47916	If you are describing a combination product then use "kit" as the dosage form.
If the NDC Product Code was previously submitted, then the product and generic name, active ingredient UNII, dosage	-The values of the data elements listed in the table cell horizontally adjacent to this cell should match those of the previous SPL for the product(s). - If aforementioned values differ from those in an SPL R3 document then request a "manual

form, active ingredient strength, product characteristics of size, shape, color and imprint code must be the same as in the most recent submission for this NDC code.	override.” - If request is not granted, you will be contacted via e-mail. - If request is granted you will NOT be notified.
If the code is C73603 or C73604, then the id root must be 2.16.840.1.113883.3.149	If the marketing category is OTC monograph final or OTC monograph not final, then choose “Regulatory Citation” as the “Application or citation number code system.” Include a monograph citation number using the correct format (e.g. “part352”)
If the code is C73583, C73584, C73585, C73588, C73593, C73594, C73605, C75302, C80438, C80440, C80441, or C80442, then the id root is 2.16.840.1.113883.3.150.	If the marketing category is ANADA, ANDA, BLA, Conditional NADA, NADA, NDA, NDA authorized generic, Exempt device, Humanitarian Device Exemption, IND, Premarket Application, or Premarket Notification, then choose “Application” as the “Application or citation number code system.” Enter a six-digit application number preceded by the marketing category prefix (e.g. NDA013444)
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there is no id.	If the marketing category is bulk ingredient, medical gas, export only, unapproved drug other, unapproved homeopathic, or unapproved medical gas DO NOT enter an application number and DO NOT include an “application or citation number code system.”
If the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C), then the marketing category is: C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), C73614 (unapproved homeopathic) or C73627 (unapproved drug other).	If the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C, then the marketing category is: ANADA, Conditional NADA, NADA, unapproved homeopathic or unapproved drug other.

<p>If the marketing category is C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), then the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C)</p>	<p>If the marketing category is ANADA, Conditional NADA, NADA, then the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C</p>
<p>If the marketing category is C73626 (bulk ingredient), then the document type is 53409-9 (bulk ingredient)</p>	<p>If the marketing category is bulk ingredient, then the document type is bulk ingredient</p>
<p>If the document type is 53409-9 (bulk ingredient), then the marketing category is C73626</p>	<p>If the document type is bulk ingredient, then the marketing category is bulk ingredient</p>
<p>Invalid content was found starting with element 'ingredient'. One of '{"urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.</p>	<p>Delete all of the packaging description information and enter again.</p> <p>To avoid this error, enter all ingredient information and then add package description</p>
<p>Active moiety name does not include any of the names in the Active moiety validation (counter ion) list except if the word appears by itself optionally followed by “cation” or “anion” or “ion”.</p>	<p>Do not include names in the active moiety counter-ion list (labeled “counter-ion validation” located in the Additional Validation Files located on this web page: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm unless word appears by itself optionally followed by “cation” or “anion” or “ion”.</p>

Invalid content was found starting with element 'asEquivalentEntity'. One of '{ "urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.	<p>There is a problem with the NDC Source Code.</p> <p>Delete the NDC Source Code from the file.</p> <p>Ensure that are using an up to date version of the listing SPL Xforms. If using version 1.02 or older then download a later version and create a completely new SPL document.</p>
There must not be empty or incomplete elements except, in certain circumstances, code, state, title, text, and time (an id must have a root, a code must have a code system).	Ensure that there are no empty fields
General SPL Errors	
Error Message	Solution
One id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension	<p>Enter the DUNS Number in the DUNS Number field.</p> <p>If DUNS Number is included, then ensure that there are no hyphens in the DUNS Number and that no spaces are entered (with the keyboard space bar) before or after DUNS Number.</p>
A submission must contain only the SPL file whose name ends in '.xml' and associated image files whose names end in '.jpg'.	<p>The file extension of the SPL document should be “.xml” (lower case letters only)</p> <p>The file extension of the JPEG image files should be “.jpg” (lower case letters only)</p> <p>DO NOT include PDF, Excel or Word documents in the folder with the SPL or image files.</p>
All image files associated with the SPL document must be actually referenced from that SPL document.	Ensure that all files included in the folder are referenced in the SPL document.
SPL file name must be the id root followed by ".xml"	Use the document root ID (GUID) as the name of the file (not the setId) followed by “.xml”
Value of version number must be greater than the value of any previously submitted version for the same setId	Increase the document version number by one whole number.

id must be unique across all documents	Change the document root ID (GUID)
SPL document not enclosed within a directory (folder). See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Enclose the SPL document in a folder and upload the folder containing the file via the FDA Gateway OC portal. The path name in the Gateway field should end in the folder name, not the SPL file name.
<This submission ci1257520697672.5960@lntap02_te.1.zip is incorrectly packaged, it is a ZIP file, not a directory. See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Remove SPL file and, if applicable, image files from the zip file place in a single folder and resubmit via FDA Gateway OC portal.
Value " is not facet-valid with respect to pattern '^[^s]+' for type 'cs'.	Ensure that you have completed all fields
The value " of attribute 'code' on element 'code' is not valid with respect to its type, 'cs'.	Ensure that you have completed all fields
Multiple SPL files	Include only one SPL document and, if applicable, associated image files per folder.
Extra folder layers	Send the SPL files and, if applicable, associated image files in a single folder.
There is an effective time with at least the provision of day in the format YYYYMMDD	Enter an effective time Ensure that you use the format YYYYMMDD (e.g. 20091124)
Code has two segments separated by a hyphen	Ensure that the NDC Product Code has two segments and that the segments are separated by a hyphen